

Remarks

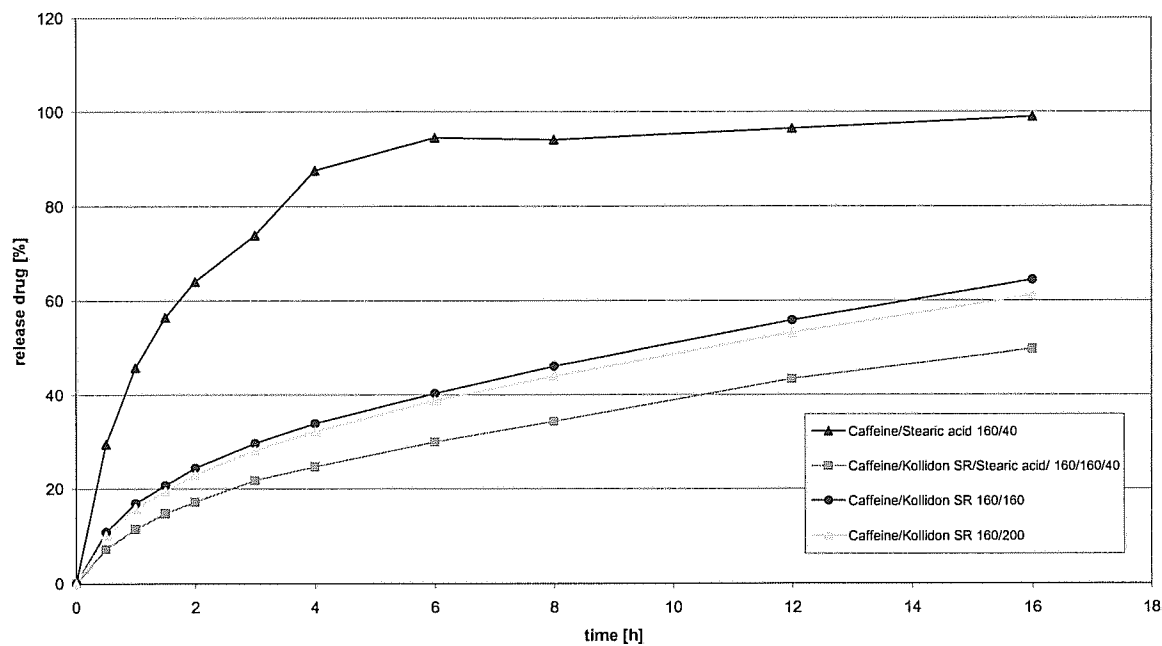
Claims 35 – 57 are pending. Claims 1 – 34 have been cancelled. The amendment to claim 1 finds support throughout the specification, for example on page 8, lines 7 – 9.

The amendment filed May 21, 2009 does not introduce new matter into the specification. The amendment merely introduced a description of US patent 5,490,990, which was referenced in the original specification.

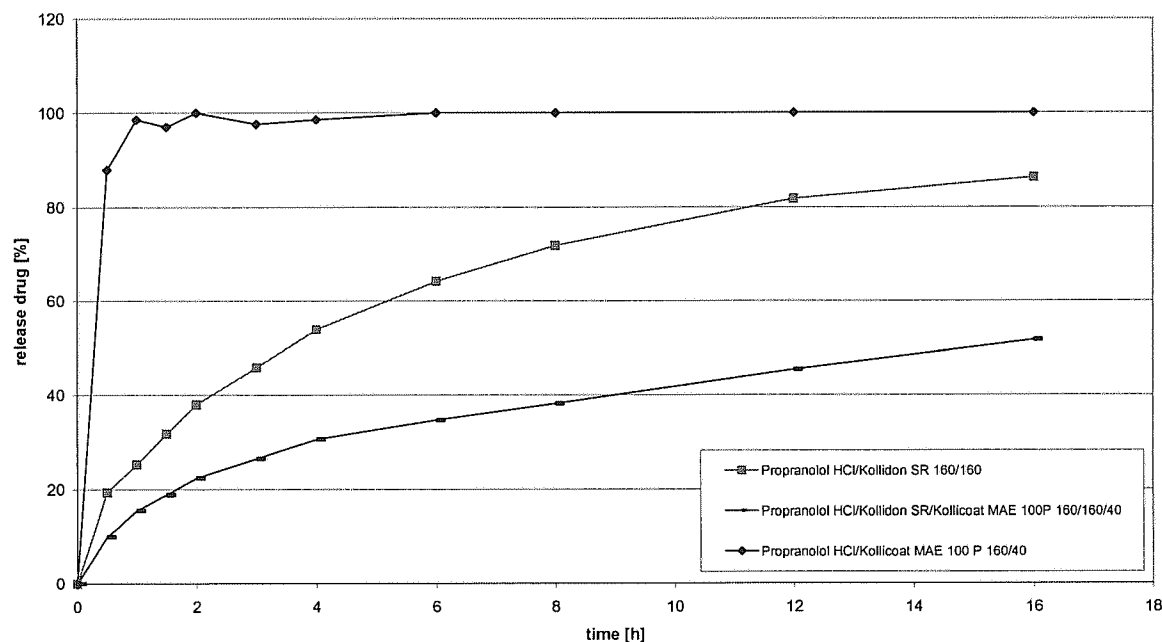
The rejection of claims 35 – 38, 40 – 54, and 57, citing 35 U.S.C §102(b) and US 4,837,032 to Ortega (hereinafter, “Ortega”). The rejection of claims 35 – 38, 40 – 52, and 54 should be withdrawn in view of the amendment to claim 35. The rejection of claims 57 and 53 should also be withdrawn, because, as explained on page 2 of the February 23, 2009 Declaration of Dr. Karl Kolter, a pre-formulated mixture obtained by spray-drying a dispersion containing two polymeric components has unique properties. In such a pre-formulated mixture, the constituents cannot be separated by mechanical operations such as for instance sieving. Also, when examined under a light microscope the two constituents cannot be separated mechanically and cannot be distinguished as two different components. An oral dosage form comprising such a pre-formulated mixture is clearly different from a dosage form lacking such a pre-formulated mixture.

The rejection of claims 25 – 28, 40 – 54, 57, and 58, citing 35 U.S.C. §103(a) and Ortega, should be withdrawn in view of the attached Declaration. The attached declaration of Dr. Karl Kolter demonstrates the synergistic effect achieved by the claimed invention is not limited to a combination of the formulated mixture of polyvinylacetate and polyvinyl pyrrolidone, Kollidon SR, with water soluble swelling polymers like hydroxypropyl methyl cellulose (HPMC). The following charts are provided to assist the Examiner in evaluating data presented in the Declaration.

Dissolution of caffeine tablets



Dissolution of Propranolol HCL tablets



The rejection of claims 25 – 28, 40 – 54, 57, and 58, citing 35 U.S.C. §103(a), DE 19709663 to Kolter (hereinafter, “Kolter”), and Ortega, should be withdrawn in view of

the attached Declaration.

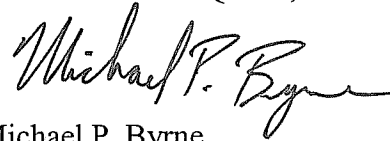
The Director is hereby authorized to charge any deficiency in fees filed, asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account 14-1437. Please credit any excess fees to such account.

The present application is in condition for allowance, and applicants respectfully request favorable action. In order to facilitate the resolution of any questions, the Examiner is welcome to contact the undersigned by phone.

NOVAK DRUCE + QUIGG, LLP  
1300 Eye St. N.W.  
Suite 1000 West  
Washington, D.C. 20005

Phone: (202) 659-0100  
Fax: (202) 659-0105

Respectfully submitted,  
NOVAK DRUCE + QUIGG, LLP

A handwritten signature in black ink, appearing to read "Michael P. Byrne". The signature is fluid and cursive, with the first name "Michael" and last name "Byrne" clearly distinguishable.

Michael P. Byrne  
Registration No. 54,015